

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

V.

SHAFFER PHARMACY, INC.; THOMAS
TADSEN; and WILSON BUNTON,

Defendants.

CASE NO.:

3 : 21 CV 22

JUDGE ZOUHARY

**DECLARATION OF MEREDITH
CARTER, DIVERSION INVESTIGATOR**

FILED TEMPORARILY UNDER SEAL

I, Meredith Carter, hereby declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States of America that the following is true and correct.

1. I am a Diversion Investigator (“DI”) with the United States Department of Justice Drug Enforcement Administration (“DEA”). I have been employed by the DEA as a DI since November 2012.

2. I attended Basic Diversion Investigator training at the DEA Academy in Quantico, Virginia from August through November 2012. This was a thirteen-week course that teaches diversion investigators the body of federal law with which registrants under the Controlled Substances Act, 21 U.S.C. §§ 801, et seq. (the “CSA”), must comply. The course also

trains diversion investigators in the practices and techniques DEA uses to determine whether registrants are in compliance with the CSA and the regulations promulgated under the CSA.

3. I have attended Advanced Diversion Investigator Training at the DEA Academy in Quantico, Virginia in July, 2019, as well as other professional development seminars.

4. Among my duties, I investigate violations of Title 21 United States Code, the Controlled Substances Act, Chapter 13, Subchapters I and II, Sections 801 through 971, and Title 21 Code of Federal Regulations, Chapter II, Part 1300 through 1321. I have done these types of civil and criminal investigations in the Regulatory Groups within DEA offices in Washington, DC; and Cleveland, Ohio.

5. The purpose of this declaration is to establish scheduling under the CSA and the prescription drug status under the federal Food and Drug Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et. seq., of certain drugs relevant to this case, as well as certain facts related to this investigation.

6. In September 2019, I joined the ongoing investigation of Shaffer Pharmacy. This is a joint investigation with the Federal Bureau of Investigation, United States Department of Health and Human Services Office of Inspector General, State of Ohio Board of Pharmacy, Ohio Bureau of Workers' Compensation, and Ohio Attorney General's Medicaid Fraud Control Unit.

7. In January 2020, I received an analysis of Shaffer Pharmacy's controlled substance purchasing history from the DEA Targeting & Special Projects Section, Reports Analysis Unit. This analysis compared Shaffer Pharmacy's purchases of reportable controlled substances to other pharmacies in its county, as well as national, state, county, zip and city averages.

8. In March 2020, I requested and received Shaffer Pharmacy's self-reported dispensing records from the Ohio Automated Rx Reporting System (OARRS). I received Shaffer Pharmacy's self-reported dispensing records for the period of January 1, 2015 through February 20, 2020.

9. In April 2020, I issued an administrative subpoena to Rx30, aka Transaction Data Systems, Inc., an electronic pharmacy management system used by Shaffer Pharmacy. In response to the subpoena, Rx30 provided backed-up records from Shaffer Pharmacy stored on Rx30 remote servers. Rx30 provided records for prescriptions filled by Shaffer Pharmacy between January 1, 2016 and April 1, 2020. Shaffer Pharmacy also maintains paper prescriptions and sign-in logs at their registered location.

10. In the following months, using Excel pivot tables, online tools, and other investigative strategies, I reviewed the records of Shaffer Pharmacy's self-reported dispensing and the Rx30 data. I found evidence of "Red Flags," or indications of potential diversion.

Scheduling of Drugs Under the Controlled Substances Act

11. The CSA provides for the regulation of controlled substances. 21 U.S.C. § 801. Every controlled substance is categorized onto one of five schedules. 21 U.S.C. § 812. Each schedule groups drugs together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. 21 U.S.C. § 811. Substances are scheduled according to the criteria set forth in 21 U.S.C. §§ 811-812.

12. Schedule I drugs are defined as drugs with no currently accepted medical use and a high potential for abuse, such as heroin, lysergic acid diethylamide (LSD), and peyote. 21 U.S.C. § 812(b)(1).

13. Schedule II drugs have a high potential for abuse, with use potentially leading to severe psychological dependence. 21 U.S.C. § 812(b)(2). These drugs are also considered dangerous. Some examples are hydrocodone, cocaine, oxycodone, and fentanyl.

14. Schedule III drugs have moderate potential for physical and psychological dependence. 21 U.S.C. § 812(b)(3). Examples include Tylenol #3/Tylenol with Codeine, ketamine, dronabinol, and anabolic steroids.

15. Schedule IV drugs have a lower potential for abuse and a lower risk of dependence than schedule I-III controlled substances. 21 U.S.C. § 812(b)(4). This category includes the majority of benzodiazepines such as Xanax, as well as Soma, Ambien, and tramadol.

16. The CSA authorizes the Attorney General to add a drug to a schedule or transfer a drug from one schedule to another by rulemaking. 21 U.S.C. § 811(a)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. § 811 to the Administrator of the DEA. 28 C.F.R. § 0.100. The final rule providing for the scheduling of a drug is published in the Federal Register.

Prescription Drug Status Under the Federal Food, Drug, and Cosmetic Act

17. Under the FDCA, certain drugs are limited to use only under a licensed healthcare practitioner's supervision and may be dispensed only upon a practitioner's prescription. *See* 21 U.S.C. § 353(b).

18. The prescription status of a particular drug may be determined by consulting the U.S. Food and Drug Administration's (FDA) publication: *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as "*The Orange Book*") (40th ed.

2020), available for download at

<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

19. *The Orange Book* identifies drug products approved by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA). *The Orange Book* lists approved drug products alphabetically by active ingredient. The lists relevant to this declaration are: Prescription Drug Products (section 3.0), Over-the-Counter Drug Products (section 4.0), and Discontinued Drug Products (section 6.0). *The Orange Book*, Contents. Each drug is accompanied by product identification information, including its active ingredient(s) and product name(s). *Id.*, 2-1.

20. My training and professional experience as a DI has given me the understanding and knowledge needed to know how to determine the prescription status of non-controlled substances and controlled substances. I have also been trained to identify a controlled substance's schedule pursuant to the Code of Federal Regulations ("C.F.R."). 21 C.F.R. §§ 1308.11-15.

21. In order to determine the prescription status of the drugs underlying Counts I and II of the Complaint in this matter, I referenced *The Orange Book's* Drug Product Lists. I searched by alphabetical order the active ingredient under which the drug product information was listed, using the Product Name Index if necessary. I then found the active ingredient in the applicable drug product list and identified whether the drug product is prescription, over the counter, or discontinued.

22. Once I determined the prescription status of the specific drugs underlying Counts I and II of the Complaint in this matter, I then determined whether the drugs containing

controlled substances as active ingredients were classified as schedule I, II, III, or IV, under the C.F.R. 21 C.F.R. §§ 1308.11-15.

23. Attached to this declaration as Exhibit A is a chart summarizing the prescription drugs underlying Counts I and II of the Complaint in this matter, the active controlled substance ingredient, the drug's schedule category under the C.F.R., common brand names for the drug, the citation to the C.F.R. that indicates the drug's schedule, and a citation to *The Orange Book* section and page. Exhibit A is a true and accurate reflection of my review of the specific drugs underlying Counts I and II of the Complaint in this matter.

The Investigation of Shaffer Pharmacy

24. Shaffer Pharmacy is a retail pharmacy in Toledo, Ohio. Shaffer Pharmacy was founded in 1961 and moved to its current location at 3900 Sunforest Court, Toledo, Ohio 43623 in 1979.

25. Thomas Tadsen has owned and operated Shaffer Pharmacy for over 40 years. Tadsen is a Registered Pharmacist (RPh). Defendant Thomas Tadsen is the owner-operator and pharmacist in charge of Shaffer Pharmacy. Thomas Tadsen was first licensed as a pharmacist in Ohio in or around August 1977. He has owned Shaffer Pharmacy since 1979.

26. Defendant Wilson Bunton is a pharmacist at Shaffer Pharmacy. Wilson Bunton was first licensed as a pharmacist in Ohio in or around June 2016. He has worked at Shaffer Pharmacy since around October 2017.

27. A review of the Employer Resource Information Center from the Ohio Department of Job and Family Services indicates that from 2017 through 2020, Shaffer Pharmacy has had a total of eleven full and part-time employees during that time, including Thomas Tadsen.

28. Since January 1, 1979, Shaffer Pharmacy has had a pharmacy license in the state of Ohio. A true and correct copy of the license, 020157850 is attached as Exhibit B to this declaration.

29. The Shaffer Pharmacy DEA registration number is AS8550243. A true and correct copy of the DEA registration is attached as Exhibit C to this declaration.

30. The DEA requires certain registrants, such as distributors of controlled substances, to report records of distributions of schedule II and schedule III controlled substances to a database called the Automated Reports & Consolidated Orders System, or "ARCOS."

31. An analysis of ARCOS data for the period of January 1, 2014 to September 30, 2019, revealed that Shaffer Pharmacy purchased the following amounts of the schedule II opioid controlled substance oxycodone:

01/01/2014 – 12/31/2014	671,200 dosage units
01/01/2015 – 12/31/2015	829,400 dosage units
01/01/2016 – 12/31/2016	817,220 dosage units
01/01/2017 – 12/31/2017	791,800 dosage units
01/01/2018 – 12/31/2018	761,700 dosage units
01/01/2019 – 09/31/2019	567,500 dosage units

32. An analysis of ARCOS data for the period of January 1, 2014 to September 30, 2019, revealed that Shaffer Pharmacy purchased the following amounts of the schedule II opioid controlled substance hydrocodone:

01/01/2014 – 12/31/2014	109,300 dosage units
01/01/2015 – 12/31/2015	132,060 dosage units
01/01/2016 – 12/31/2016	121,540 dosage units
01/01/2017 – 12/31/2017	127,300 dosage units
01/01/2018 – 12/31/2018	137,190 dosage units
01/01/2019 – 09/31/2019	106,330 dosage units

33. An analysis of ARCOS data for the period of January 1, 2014 to September 30, 2019, revealed that Shaffer Pharmacy purchased the following amounts of the schedule II opioid controlled substance oxymorphone:

01/01/2014 – 12/31/2014	45,440 dosage units
01/01/2015 – 12/31/2015	48,380 dosage units
01/01/2016 – 12/31/2016	46,440 dosage units
01/01/2017 – 12/31/2017	37,720 dosage units
01/01/2018 – 12/31/2018	24,600 dosage units
01/01/2019 – 09/31/2019	10,800 dosage units

34. An analysis of ARCOS data for the period of January 1, 2014 to September 30, 2019, revealed that Shaffer Pharmacy purchased the following amounts of the schedule III opioid controlled substance buprenorphine:

01/01/2014 – 12/31/2014	37,832 dosage units
01/01/2015 – 12/31/2015	42,334 dosage units
01/01/2016 – 12/31/2016	39,112 dosage units
01/01/2017 – 12/31/2017	30,646 dosage units
01/01/2018 – 12/31/2018	39,260 dosage units
01/01/2019 – 09/31/2019	37,086 dosage units

35. An analysis of ARCOS data for the period of January 1, 2014 to September 30, 2019, revealed that Shaffer Pharmacy purchased the following amounts of the schedule II opioid controlled substance fentanyl (minus the tradename Subsys):

01/01/2014 – 12/31/2014	10,335 dosage units
01/01/2015 – 12/31/2015	9,882 dosage units
01/01/2016 – 12/31/2016	8,222 dosage units
01/01/2017 – 12/31/2017	9,338 dosage units
01/01/2018 – 12/31/2018	7,470 dosage units
01/01/2019 – 09/31/2019	5,335 dosage units

36. An analysis of ARCOS data for the period of January 1, 2014 to September 30, 2019, revealed that Shaffer Pharmacy purchased the following amounts of the schedule II opioid controlled substance Subsys:

01/01/2014 – 12/31/2014	2.39 grams
01/01/2015 – 12/31/2015	55.89 grams
01/01/2016 – 12/31/2016	66.67 grams
01/01/2017 – 12/31/2017	21.69 grams
01/01/2018 – 12/31/2018	13.95 grams
01/01/2019 – 09/31/2019	4.18 grams

37. Based on a review of Shaffer Pharmacy's pharmacy management system, Rx30, which indicates what type of insurance, if any, patients used to pay for their prescription drugs, I know that Shaffer Pharmacy's patient mix includes Medicare, Medicaid, Worker's Compensation, and private insurance patients.

38. I estimate Shaffer Pharmacy's total current patient population at approximately 2,300 unique patients.

39. Shaffer Pharmacy's patients receive a combination of schedule II, schedule III, schedule IV, and schedule V controlled substance prescriptions, as well as non-controlled prescriptions.

40. A review of records from Shaffer Pharmacy's pharmacy management system, Rx30, for prescriptions filled between January 1, 2016 and April 1, 2020 indicates that Shaffer Pharmacy filled 227,879 prescriptions during that timeframe (including refills). In total, this record shows that 65.5% of prescriptions filled were for non-controlled drugs and 34.5% were for controlled substances. 23.6% of prescriptions filled by Shaffer Pharmacy were schedule II controlled substances, 2.7% were schedule III controlled substances, 6.6% were schedule IV

controlled substances, and 1.6% were schedule V controlled substances. It is common for legitimate pharmacies to have a ratio of approximately 20% of controlled to 80% non-controlled substances. Higher ratios of controlled substances can be reasonable for specialty pharmacies (such as those servicing hospice patients), but Shaffer Pharmacy does not fall into that category. Shaffer Pharmacy's ratio of controlled substances to non-controls dispensed is an outlier and far exceeds the average; Shaffer Pharmacy dispenses a higher proportion of schedule II controlled substances than most pharmacies total proportion of controlled substances.

41. A breakdown of the prescriptions dispensed by Shaffer Pharmacy per Rx30 pharmacy management system data for the period of January 1, 2016 to April 1, 2020, is as follows:

Year 2016		
Non-controlled	29797	62.77%
Schedule II	12195	25.69%
Schedule III	1229	2.59%
Schedule IV	3636	7.66%
Schedule V	613	1.29%
Total RX	47470	100.00%

Year 2017		
Non-controlled	33983	62.55%
Schedule II	14225	26.18%
Schedule III	1528	2.81%
Schedule IV	3788	6.97%
Schedule V	808	1.49%
Total RX	54332	100.00%

Year 2018		
Non-controlled	37794	65.90%
Schedule II	13564	23.65%
Schedule III	1479	2.58%
Schedule IV	3598	6.27%
Schedule V	918	1.60%
Total RX	57353	100.00%

Year 2019		
Non-controlled	38568	67.55%
Schedule II	12492	21.88%
Schedule III	1651	2.89%
Schedule IV	3394	5.94%
Schedule V	990	1.73%
Total RX	57095	100.00%

Jan - Apr 2020		
Non-controlled	9175	78.90%
Schedule II	1245	10.71%
Schedule III	353	3.04%
Schedule IV	647	5.56%
Schedule V	209	1.80%
Total RX	11629	100.00%

42. Shaffer Pharmacy's self-reported dispensing and the records entered into the Rx30 data management system revealed a slight divergence, indicating possible errors in reporting or data entry at the pharmacy, or post-reporting changes to the pharmacy management record. These differences could be caused by old Rx30 data expiring or being purged from the remote server, such as when a patient dies or is no longer active at the pharmacy. These differences could also be caused by variations in reporting dates versus dispensing dates, or for prescriptions that are marked as dispensed and then returned to the shelves when the patient does not pick up the prescription. Some pharmacy management systems also assign an Rx number to

pharmacies selling directly to practitioners for office stock. These differences do not significantly change the values or percentages listed above.

43. A review of Shaffer Pharmacy's self-reported dispensing for prescriptions filled between January 1, 2015 and February 20, 2020 indicates Shaffer Pharmacy filled 103,086 controlled substance prescriptions (including refills).

44. These 103,086 controlled substances prescriptions were shown to be dispensed during the following time frames:

Year 2015		
Total c/s with refills	22,219	100%
Total unique	19,738	
Schedule II	15,395	69.29%
Schedule III	1,920	8.64%
Schedule IV	4,296	19.33%
Schedule V	608	2.73%

Year 2016		
Total c/s with refills	21,417	100%
Total unique	19,459	
Schedule II	14,996	70.02%
Schedule III	1,529	7.14%
Schedule IV	4,179	19.51%
Schedule V	712	3.32%

Year 2017		
Total c/s with refills	20,010	100%
Total unique	17,844	
Schedule II	13,977	69.85%
Schedule III	1,505	7.52%
Schedule IV	3,726	18.62%
Schedule V	801	4.00%

Year 2018		
Total c/s with refills	19,440	100%
Total unique	17,279	
Schedule II	13,482	69.35%
Schedule III	1,470	7.56%
Schedule IV	3,574	18.38%
Schedule V	914	4.70%

Year 2019		
Total c/s with refills	18,432	100%
Total unique	16,241	
Schedule II	12,431	67.44%
Schedule III	1,638	8.89%
Schedule IV	3,375	18.31%
Schedule V	988	5.36%

1/1/2020-2/20/2020		
Total c/s with refills	1,568	100%
Total unique	1,072	
Schedule II	668	42.60%
Schedule III	190	12.12%
Schedule IV	382	24.36%
Schedule V	121	7.72%

“RED FLAGS”

45. 21 C.F.R. § 1306.04(a) states that:

a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but **a corresponding responsibility rests with the pharmacist who fills the prescription.** An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the CSA (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

[emphasis added].

46. Red flags are behaviors that indicate a potential diversion of controlled substances from licit to illicit channels, and that the prescriptions in question may not be issued in the usual course of professional practice, or for a legitimate medical purpose. Often, a patient or prescription may exhibit multiple red flags, indicating an even higher likelihood that the controlled substances are being obtained without medical necessity.

47. An analysis of Shaffer Pharmacy's ordering and dispensing history has revealed a number of unexplained red flags, indicating potential diversion. I divided these red flags into four general categories: dispensing, purchasing, handling of the drug Subsys, and distributor notifications.

"RED FLAGS: Dispensing"

48. It can be a red flag when patients receive combinations of controlled substances in unusual patterns or "cocktails" that are associated with abuse and overdose, and for which there is limited medical value. Certain combinations of controlled substances can have a synergistic effect with one another, magnifying and potentiating the side effects, eliciting euphoria (a "high") that is greatly sought after by abusers of controlled substances, and greatly increasing the chances of overdose and death. Dangerous or frequently abused cocktails include:

- The "Holy Trinity" – a colloquial term for the combination of an opiate, a benzodiazepine, and carisoprodol (brand name Soma). This combination is one of the most commonly seen cocktails of abuse. Opiates on their own have a depressive effect on the central nervous system. Benzodiazepines also inhibit the central nervous system. The addition of muscle relaxant carisoprodol is especially dangerous, as the patient taking this combination may not be able to

maintain a patent airway. In combination with respiratory depression resulting from the opiate and benzodiazepine, there is a high risk of respiratory failure and death.

- An opiate, a benzodiazepine, and a stimulant – A stimulant may be used to counteract unwanted depressive side-effects for individuals abusing a combination of opiates and benzodiazepines or taking higher quantities of these substances than medically necessary. This is sometimes referred to as “taking an upper with a downer.” According to a Boston Medical Center journal article published in 2019, medical professionals report seeing a “fourth wave” in the opioid epidemic, which involves the use of stimulants alongside opioids as a popular cocktail choice. Combining stimulants with opiates and other depressants can create a feeling of normalcy in patients who nevertheless can experience tremors and delayed reaction times, leading to a higher risk of workplace and road accidents. Additionally, the risk of overdose is increased, and can change the physiological reaction to overdose antidotes such as naloxone, making treatment for the overdose less effective.
- An opiate, a benzodiazepine, a muscle relaxant, and a sedative – This combination is relatively rare and very dangerous, as it involves four separate categories of drugs that have depressive effects on the central nervous system and autonomic responses. These drugs interact with each other synergistically and may have unpredictable interactions that pharmacists acting in the usual course of their professional practice would be concerned with.

- An opiate and a benzodiazepine – A combination of opiate and benzodiazepine, with or without other drugs, is associated a high risk of overdose hospitalization and death. More than thirty percent of opiate overdoses (possibly around forty percent, according to some studies) also involve the use of a benzodiazepine. Studies have shown that the overdose death rate among patients receiving both types of medications is ten times higher than among those only receiving opioids. In 2016, the Center for Disease Control and Prevention (CDC) recommended physicians avoid prescribing benzodiazepines concurrently with opioids whenever possible, and the prescriptions for both types of medications now carry FDA “black box” warnings highlighting the dangers of using these two drugs at the same time.
- An opiate and buprenorphine – Buprenorphine is an opiate agonist specifically prescribed to treat individuals with a clinically documented history of opiate abuse and physiological and/or psychological dependence to opiates. Buprenorphine products often contain naloxone, a partial opiate antagonist, which is designed to counteract the “high” a potential abuser would seek if they crushed and snorted or injected the buprenorphine. Prescribing an opiate to a person with a documented history of opiate abuse and dependence, especially if they are already taking the opiate buprenorphine for opiate dependence, should be undertaken with caution due to the high risk for abuse and diversion.

49. Shaffer Pharmacy’s self-reported dispensing during the time frame of 1/1/2015 - 02/20/2020 showed eighteen patients received “Holy Trinity” prescriptions (from the same prescriber, with overlapping fill dates) filled at Shaffer Pharmacy. Shaffer Pharmacy made over

one hundred groups of “Holy Trinity” fills, not including refills, during this time frame. One example is J.S., who received at least seven “Holy Trinity” fills (three to ten controlled substance fills of sixty to ninety dosage units each) from Shaffer Pharmacy, dispensed between February 20, 2015 and July 14, 2015, again May 31, 2016 through June 29, 2016, again on March 17, 2017, and October 16, 2018 through February 15, 2019. Another set of examples is F.Sc. and S.Sc., who received fifteen and three groups of “Holy Trinity” prescriptions respectively, filled between January 15, 2015 and July 22, 2019. This pair of patients were found to be a married couple via public records search. This is indicative of another red flag, which is a husband and wife receiving the same unusual cocktail of controlled substances, since it would be unlikely that two members of the same family have the same medical needs. Furthermore, while F.Sc. received all his Trinity prescriptions (and all controlled substance prescriptions) in 2015 from a single family practice prescriber, S.Sc. received controlled substance prescriptions from five prescribers in 2015 alone, including an additional benzodiazepine (Clonazepam 2mg) from one prescriber concurrent with her “Holy Trinity” fills from a separate prescriber. This is indicative of “doctor shopping” behavior (see ¶¶ 56-58 below). In late 2015, S.Sc. stopped receiving “Holy Trinity” fills, and began receiving prescriptions for buprenorphine products, indicating opiate use disorder (see section on buprenorphine below), after receiving an opiate fill written by yet another prescriber. S.Sc. also received her first “Holy Trinity” fills paid for by commercial insurance, but began to have a mix of payment types, indicating insurance would not approve of these fills. In summary, there is a plethora of evidence that these “Holy Trinity” fills for S.Sc. were not for a legitimate medical purpose in the usual course of professional practice and that Shaffer Pharmacy ignored multiple red flags in filling S.Sc.’s controlled substance prescriptions.

50. Shaffer Pharmacy's self-reported dispensing during the time frame of 1/1/2015 - 02/20/2020 revealed eighteen patients who received an opiate, benzodiazepine, and stimulant cocktail (written by the same prescriber, with overlapping fill dates), filled at Shaffer Pharmacy. Shaffer Pharmacy made sixty-nine opiate, benzodiazepine, and stimulant group fills, not including refills. One example is C.G. who received seventeen group fills prescribed between 10/20/2014 to 11/12/2019 and dispensed by Shaffer Pharmacy between 1/8/2015 to 12/2/2019.

51. Shaffer Pharmacy's self-reporting dispensing during the time frame of 01/01/2015 - 02/20/2020 showed at least six patients received an opiate, benzodiazepine, muscle relaxant, and sedative cocktail (written by the same prescriber, with overlapping fill dates), filled at Shaffer Pharmacy. Shaffer Pharmacy made eleven group fills, not including refills. One example was D.M., who received five opiate, benzodiazepine, muscle relaxant, and sedative group fills prescribed between 6/9/2015 and 3/23/2018 and dispensed by Shaffer Pharmacy between 8/31/2015 and 3/24/2018. These prescriptions were all shown as written by the same family practice physician (not a pain management or palliative care specialist) until 5/2/2017, and then by a different prescriber from 5/18/2017 until 3/23/2018. Additionally, according to publicly available information, D.M. died 3/23/2018, the same day his last prescription (Alprazolam 1 mg, 60 count) in the final opiate, benzodiazepine, muscle relaxant, and sedative group was prescribed, and one day before Shaffer Pharmacy reported filling that prescription. D.M.'s obituary states that he "passed away unexpectedly."

52. Shaffer Pharmacy's self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 revealed at least 580 patients received an opiate and benzodiazepine (opiate/benzodiazepine) combination (with overlapping fill dates), filled at Shaffer Pharmacy. Shaffer Pharmacy made approximately 3,100 opiate/benzodiazepine combination fills during this

time frame. Examples include R.T., who received nineteen opiate/benzodiazepine combination fills from Shaffer Pharmacy written between 1/22/2015 and 2/5/2020, by four successive prescribers. Other examples include D.Sk. and G.Sk., a husband and wife who received two and twenty-four respective opiate/benzodiazepine combination fills and B.Sl. and C.Sl. (another husband and wife pair), who received fifty-one and forty-six respective opiate/benzodiazepine combination fills.

53. Shaffer Pharmacy's self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 revealed at least fifty-five patients received opiate and buprenorphine (opiate/buprenorphine) combination fills, filled at Shaffer Pharmacy. Shaffer Pharmacy made over 130 opiate/buprenorphine combination fills, during this time frame. An example is J.Tu. who received twelve opiate/buprenorphine combination fills from Shaffer Pharmacy, filled between 3/14/2017 and 8/8/2018. These opiate/buprenorphine combinations were written by three different prescribers, the latter of two alternating, and on at least one occasion, the two prescribers wrote the opiate and buprenorphine prescriptions on the same day. Another example is R.Si. who received eleven opiate/buprenorphine combination fills from Shaffer Pharmacy, including sixty- and ninety-day supplies of the buprenorphine product Belbuca, a fifty-six-day supply of the opioid oxycodone-acetaminophen 10/325, and ninety- and one-hundred-and-twenty-day supplies of the opioid Nucynta.

54. It can be a red flag when multiple family members living in the same household receive multiple opioid prescriptions. While single, short term opioid therapy may be prescribed to multiple family members for acute conditions such as dental work or injury, multiple opioid prescriptions for multiple members of a household are associated with a higher risk of patient diversion, drug seeking behavior, and formation of opioid dependence disorder. During the time

frame of 01/01/2015 - 02/20/2020, Shaffer dispensed multiple opioid prescriptions to over 100 sets of patients with the same surname, living at the same address. Over thirty sets of patients met the above criteria and received at least one hundred combined opioid prescriptions filled at Shaffer, with each member receiving at least five opioid prescriptions. For example, M.F. and L.F. received 104 opioid prescriptions written between March 2015 and June 2019, and ninety opioid prescriptions between June 2015 and June 2019 respectively.

55. It may be a red flag when a pharmacy allows early refills of controlled substance prescription medications because it indicates that the patient is taking a higher dose of the control than prescribed, or that it is being sold or stolen (i.e., diverted). It is also an indication of drug-seeking behavior and a possible sign of abuse and dependence. Shaffer Pharmacy's self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 showed eighteen patients received early refills from a single prescriber, where the controlled substance dispensed was identical in name and strength, and there were at least eight days left of the previously dispensed drugs. An example is P.St., who received ninety-day supplies of zolpidem tartrate 5mg, on 8/5/2016, 10/11/2016 and 12/16/2016 (270 dosage units in 133 days), and then again on 9/6/2018, 10/22/2018 and 12/28/2018 (270 dosage units in 113 days). Another example is R.F., who received thirty-days supplies of Dilaudid 4mg on 4/17/2015, 4/27/2015, 5/18/2015, and 6/4/2015 (360 dosage units in 48 days), as well as a second opiate, oxycodone HCL 30mg, on 4/27/2015, 5/18/2015, and 6/4/2015 (810 dosage units in 38 days). This pattern of escalation, with the addition of a second opiate, is also a red flag.

56. It may be a red flag when a patient receives multiple opiate prescriptions from more than one prescriber in a short period of time. This behavior is known as "doctor shopping," and is a red flag because it shows the patient is seeking out controlled substances when there is

no legitimate medical need. It may indicate that a patient is deceiving prescribers by obtaining multiple prescriptions without their knowledge, or that the prescriber has noticed signs of drug abuse or diversion and becomes no longer willing to write controlled substance prescriptions for that patient.

57. Shaffer Pharmacy's self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 showed over 590 patients received at least one prescription for an opiate controlled substance from Shaffer Pharmacy within fifteen days of Shaffer Pharmacy dispensing an opiate controlled substance prescription for them written by a different prescriber. An example is A.C., who received oxycodone-acetaminophen on 9/18/2018, written by one prescriber, hydrocodone-acetaminophen on 9/25/2018, written by a second prescriber, and tramadol-acetaminophen on 10/9/2018, written by a third prescriber. Shaffer Pharmacy also dispensed many prescriptions such as these to patient A.C. on numerous other occasions, including various opiates on 9/11/2019, 9/16/2019, 9/23/2019 and 9/25/2019, written respectively by four additional prescribers.

58. Shaffer Pharmacy's self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 showed over 360 patients received three or more prescriptions from three or more prescribers within three months. An example is D.L., who received both Oxycodone and Methadone from three prescribers, written between 2/16/2016 and 4/20/2016. Another example is D.Mc., who received hydrocodone -acetaminophen written on 6/16/2016, 8/31/2016, 9/1/2016 and 9/13/2016 by three different prescribers, as well as on other occasions, from these prescribers and others.

59. It may be a red flag when a patient goes to a pharmacy to fill more than one prescription and uses cash to pay for one prescription, but not another. Sometimes there are

legitimate reasons for doing so, i.e., cash discount or coupons. However, it also may indicate that the patient is attempting to draw attention away from this prescription by not having it billed to their insurance, or that their insurer will not pay for the prescription due to perceived lack of medical necessity or legitimate medical purpose. Shaffer Pharmacy's self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 showed approximately 160 patients used cash to pay for one prescription but not another at Shaffer Pharmacy. These patients had partial cash fills for controlled substances at least 618 times. An example is D.S., who on twenty-eight occasions between 7/19/2017 and 2/3/2020, received an opiate paid for by commercial insurance or Worker's Compensation, while at the same visit receiving a benzodiazepine (Diazepam) paid for out-of-pocket. This combination of controlled substances taken together is also a red flag, as described in the dangerous cocktail paragraphs above.

60. It may be a red flag when there is a great distance between a patient's home address and the pharmacy where controlled substance medications are dispensed for them, when there are closer options available. According to a survey by the National Association of Chain Drug Stores, nine out of ten patients live within five miles of a community pharmacy (in metropolitan areas, the average is less than two miles). According to a different survey, the most important criteria patients cited for choosing a pharmacy was convenience/location, followed distantly by customer service. Rx30 records for controlled substance prescriptions filled between January 1, 2016 and April 1, 2020 revealed that Shaffer Pharmacy filled prescriptions for patients with home addresses in approximately 232 cities in 14 states. Almost 1.5% of these prescriptions were dispensed to patients with listed addresses more than 100 miles away, and 8% of the prescriptions were for patients with addresses 30 or more miles away. Examples include fifty-one prescriptions filled at Shaffer Pharmacy for patients in Schenectady, New York (569

miles from Shaffer Pharmacy), thirty-one prescriptions filled for patients in West Sacramento, California (2,264 miles away), and seventeen prescriptions for patients in Hot Springs Village, Arkansas (860 miles away).

61. The following table shows patient cities at least 30 miles from Shaffer Pharmacy, for which they filled at least one hundred prescriptions:

Patient City	State	Total # of Prescriptions filled at Shaffer	Approximate miles from Shaffer
DELTA	OH	796	30.6
CRESTLINE	OH	326	106
WAUSEON	OH	227	40.6
MILAN	MI	205	38.3
DEFIANCE	OH	175	57.6
KENTON	OH	174	73.4
FINDLAY	OH	158	45
FOSTORIA	OH	157	42.2
MONTPELIER	OH	155	63.5
TIFFIN	OH	151	53.1
LIMA	OH	150	77.5
FREMONT	OH	144	38
BROOKLYN	MI	142	62.5
BELLEVILLE	MI	125	49.3
MARION	OH	123	95.1
CYGNET	OH	115	31
LAKEVIEW	OH	112	101.8
CENTER LINE	MI	101	73.6

62. It may be a red flag when there is a great distance between the location of a prescribing practitioner, and the pharmacy where the controlled substance prescription is dispensed, when there are closer options available. Shaffer Pharmacy's Rx30 records for prescriptions filled between January 1, 2016 and April 1, 2020 revealed that Shaffer Pharmacy filled prescriptions for practitioners located in approximately 106 cities in 14 states. Over 1% of the total number of controlled substance prescriptions dispensed were for prescribers over 100

miles from Shaffer Pharmacy, and over 6% were for prescribers over 50 miles away. Examples include 164 prescriptions filled for prescribers in Dublin, Ohio (122.3 miles away), 120 prescriptions filled for a prescriber in South Bend, Indiana (155.5 miles away), and 22 prescriptions for a prescriber in Marco Island, Florida (1,290.6 miles away). In this last case, the patient also paid for their prescriptions with a mix of commercial insurance and cash, which is a red flag described in paragraph 59.

63. It can be a red flag when patients receive prescriptions that amount to high daily MME (morphine milligram equivalent). MMEs are a way of assessing how high the dose of opioids a patient is taking in a way that is standardized across different drugs, formulations, strengths, and dosage forms. MME calculators may be found for free online, including a mobile app from the CDC available on Google Play and the Apple Store. These calculators take the drug, the dosage, and the number of doses per day, and give a score that can be compared across drug types and strengths. For instance, a patient receiving Oxycontin 20mg, 60 count, 30 day supply (i.e., 2 doses per day), has a MME of 60. This is the same calculated MME/day as fentanyl transdermal patch, 25 mcg/hr, one patch every three days. On the other hand, a patient receiving 20mg hydrocodone, instead of Oxycontin, with the same sixty count, thirty day supply, has a MME of 40. The MME score for patients receiving more than one opioid is the sum of each prescription's MME.

64. According to the CDC Guideline for Prescribing Opioids for Chronic Pain, which is also found as a “quick link” on their free MME calculator, “[c]linicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents

(MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.”

65. A review of Shaffer Pharmacy’s self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 revealed sixty-five patients with an average of 500 MME per day or greater from prescriptions filled at Shaffer Pharmacy. Eighteen patients had MMEs of 1,000 or greater. One example is R.J., who received sixty-six prescriptions filled at Shaffer Pharmacy written between January and August, 2015, with an average MME per day of 1,391.3.

66. A review of Shaffer Pharmacy’s self-reported dispensing during the time frame of 01/01/2015 - 02/20/2020 revealed that in over fifty cases, patients received a rapid escalation of MMEs – three prescription fills, within three months, where the MME doubled from the previous fill. A typical example is D.Bu., who was dispensed 61 MMEs/day on 8/31/2015, 180 MMEs/day on 9/14/2015, and 431 MMEs/day on 10/13/2015.

67. There were also other patients whose MMEs/day were made higher by early fills. Early fills allow for a patient to have access to additional narcotics before they finish their previous prescription. In such a case the daily MME is actually the sum of both prescriptions’ individual MME. One such example is R.A. who was dispensed 60 MMEs/day on 10/29/2015 (oxycodone 10mg, 120 dosage units for thirty days), and received another prescription just six days later on 11/4/2015 (Oxycontin 30mg, 90 dosage units for thirty days). The MME/day for this prescription alone was 135 MMEs/day, but on the three weeks that overlapped, R.A. had available MME of 195 MMEs/day. On 11/30/2015, twenty-six days later, she received another fill of oxycodone 10mg, 120 dosage units and oxycodone ER 40mg 90 dosage units which put her at 240 MMEs/day (plus 135 for a total of 375 during the days of overlap). These sudden

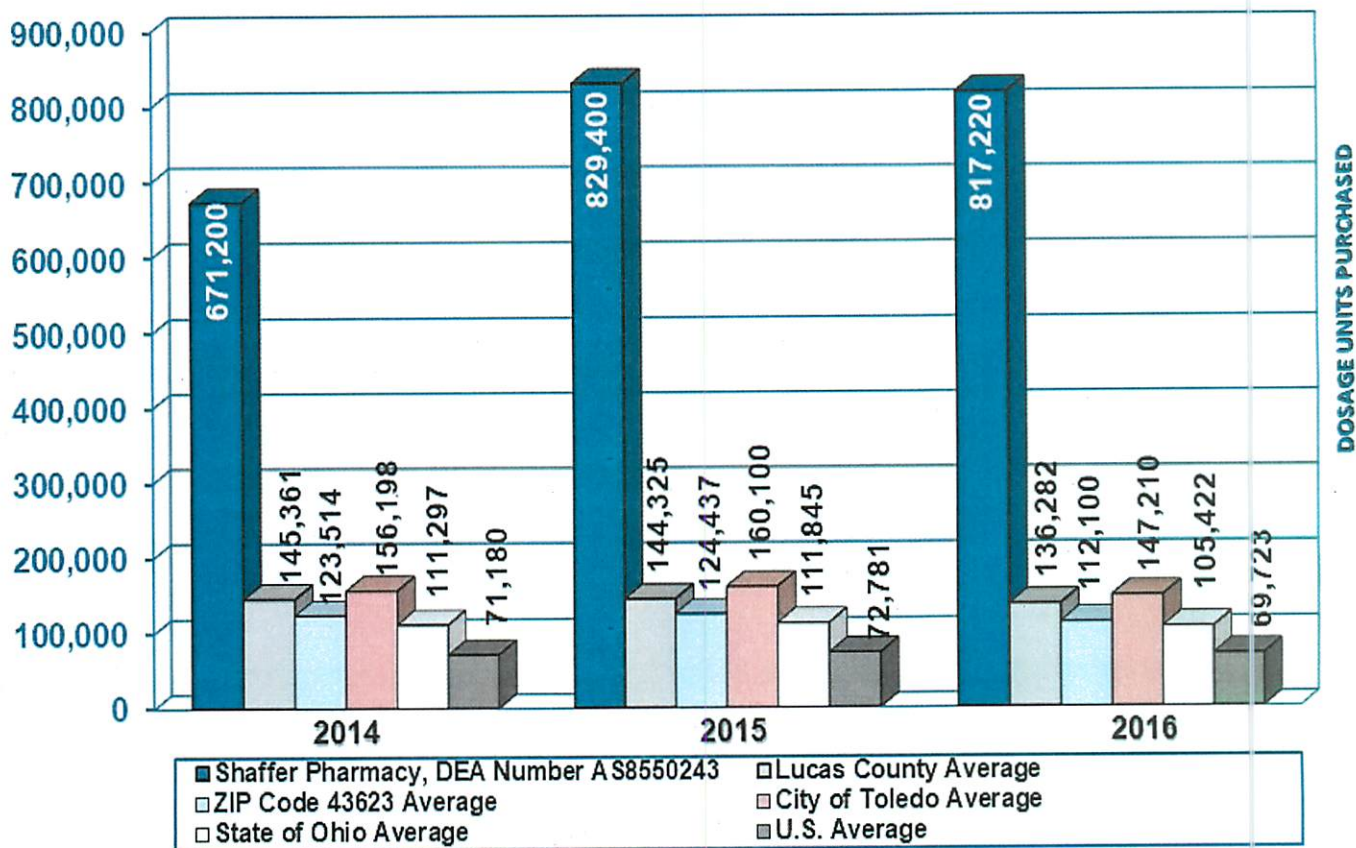
increases and early availability of high MMEs greatly increases the risk of overdose, as well the possibility that the patient is diverting/selling their medication.

“RED FLAGS: Purchasing”

68. It can be a red flag when a pharmacy purchases greater than average amounts of controlled substances without any reason for why the amounts are so high, such as proximity to major medical center, or having a specialized business model (such as a mail order or long-term care pharmacy). Being an “outlier” in purchases of high amounts of controlled substances is an indication of possible diversion.

69. A comparison was made of Shaffer Pharmacy’s purchasing history to purchasing averages for other pharmacies for the period of January 1, 2014 to September 30, 2019. Shaffer Pharmacy’s purchases of the schedule II opioid controlled substance oxycodone, in dosage units, are compared to pharmacy averages in the following charts:

Yearly Comparisons of Oxycodone Purchases by Pharmacies Jan 2014 to Dec 2016

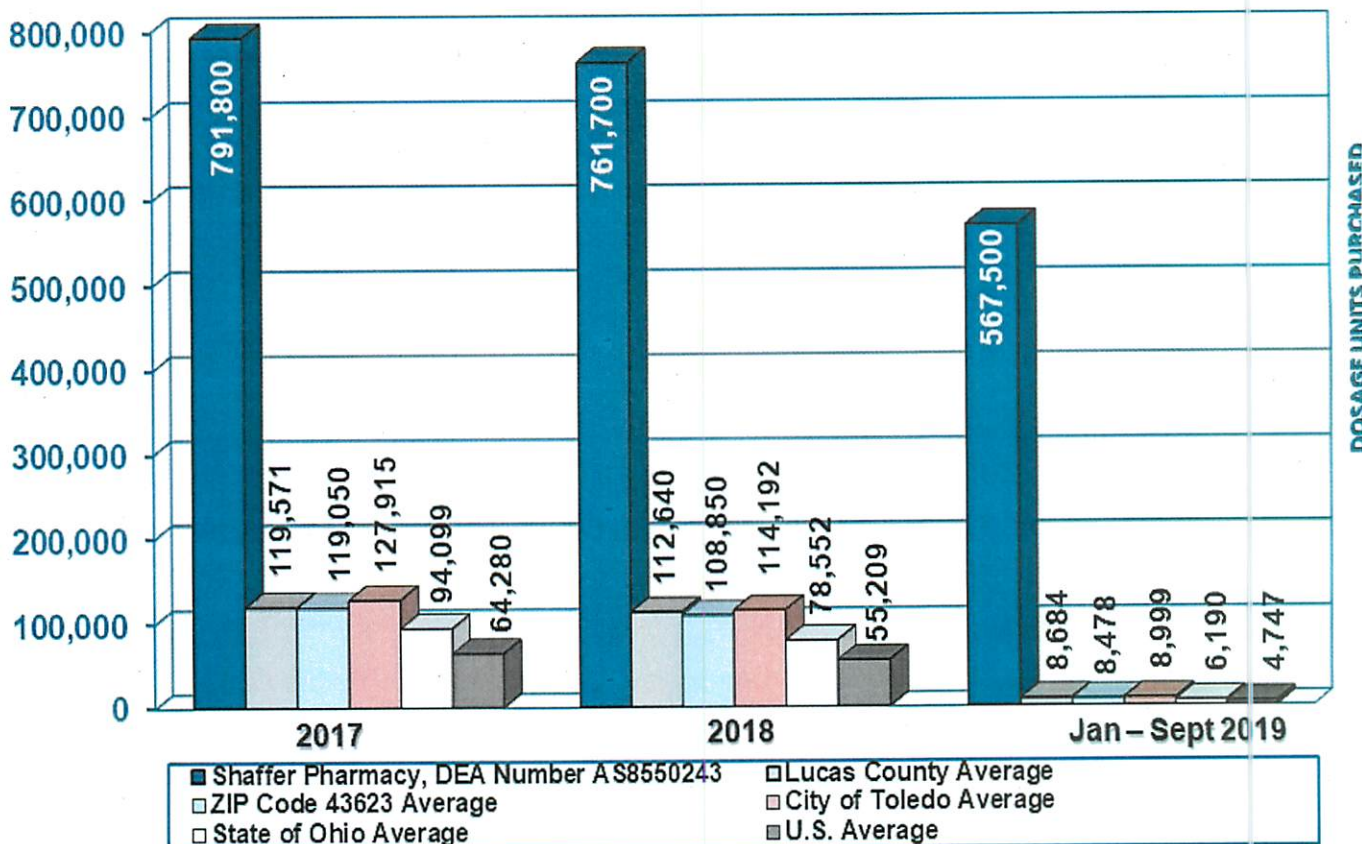


*Targets purchases excluded from averages

Drug Enforcement Administration, Diversion Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

Yearly Comparisons of Oxycodone Purchases by Pharmacies Jan 2017 to Sept 2019



*Targets purchases excluded from averages

Drug Enforcement Administration, Diversion Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

70. The charts above shows that Shaffer Pharmacy is an extreme outlier for purchases of oxycodone compared to the nationwide, citywide, statewide, Zip code, and countywide averages. In the majority of comparisons, Shaffer Pharmacy purchased five to ten times the average amount of oxycodone for a pharmacy.

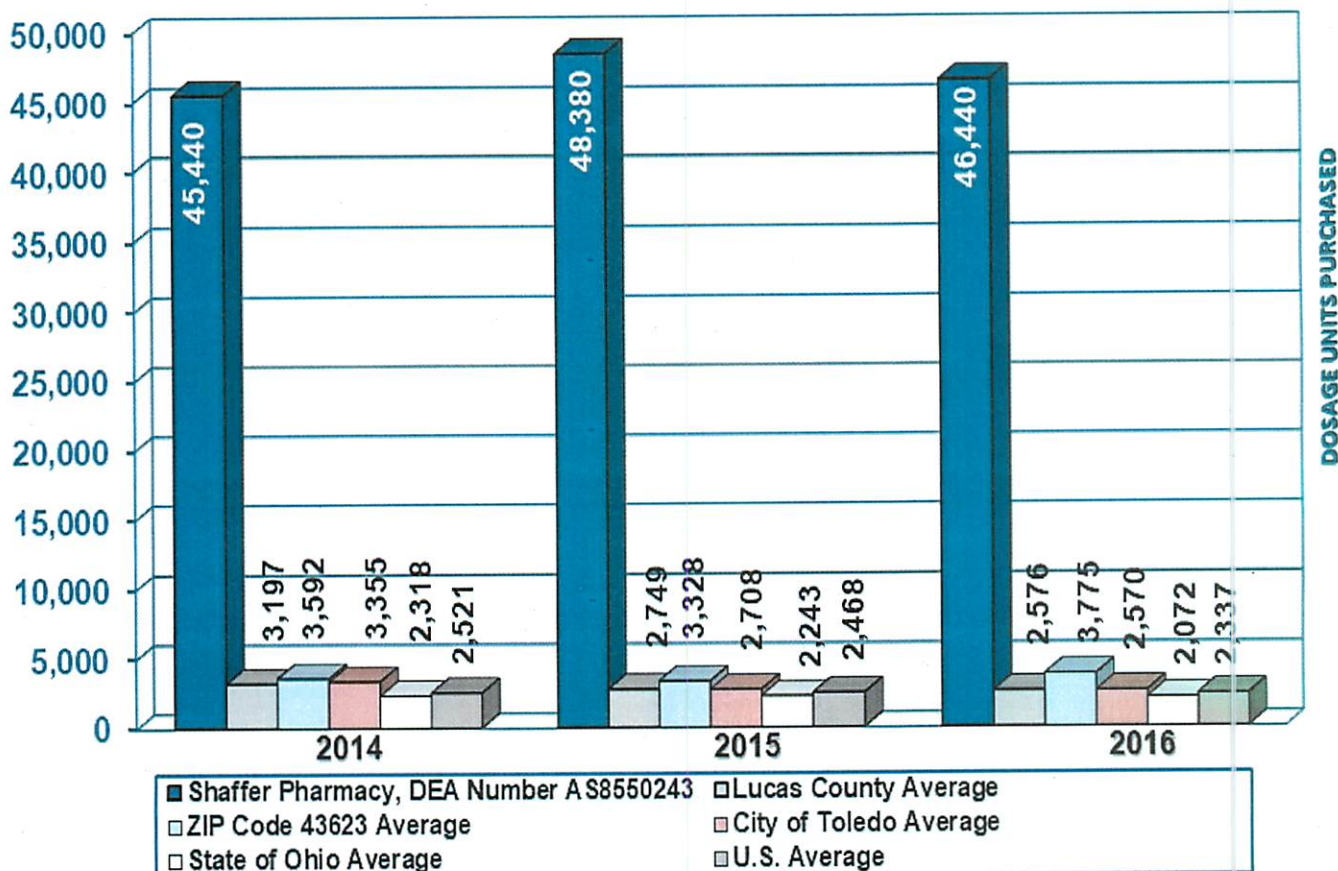
71. A comparison was made of the oxycodone purchasing history of Shaffer Pharmacy to other pharmacies in Lucas County, Ohio, where Shaffer Pharmacy is located. In 2014, Shaffer Pharmacy was the second highest purchaser of oxycodone in Lucas County, with

671,200 dosage units, compared with 565,400 to the third highest purchaser, and 435,300 to the fourth highest. The highest purchaser of oxycodone in Lucas County in 2014 was Heartland Healthcare Services (Heartland), with 1,768,800 dosage units. Heartland is a closed door, long-term care pharmacy, which according to its website, fills “nearly 5 million prescriptions per year” and “services 20,000 beds in ten states.” As a long-term care pharmacy, Heartland services an elderly population in nursing homes, post-surgical and injury rehabilitation centers, and palliative care/hospice patients. Due to the large patient population, comprised of medically fragile and/or medically needy patients, there is an explanation for why Heartland would be by far the top purchaser of oxycodone and other opioid controlled substances in its area.

72. In the years after 2014, the gap between Heartland’s reported purchases of oxycodone and Shaffer Pharmacy’s reported purchases shrank, and for the reporting period of January – September 2019, Shaffer Pharmacy overtook Heartland as the top purchaser of oxycodone, with 567,500 dosage units for Shaffer Pharmacy versus 542,200 for Heartland. In contrast, the third and fourth highest pharmacies in Lucas County for January – September 2019 purchased 250,600 and 224,800 dosage units respectively.

73. A comparison was made of Shaffer Pharmacy’s purchasing history to purchasing averages for other pharmacies for the period of January 1, 2014 to September 30, 2019. Shaffer Pharmacy’s purchases of the schedule II opioid controlled substance oxymorphone, in dosage units, are compared to pharmacy averages in the following charts:

Yearly Comparisons of Oxymorphone Purchases by Pharmacies Jan 2014 to Dec 2016

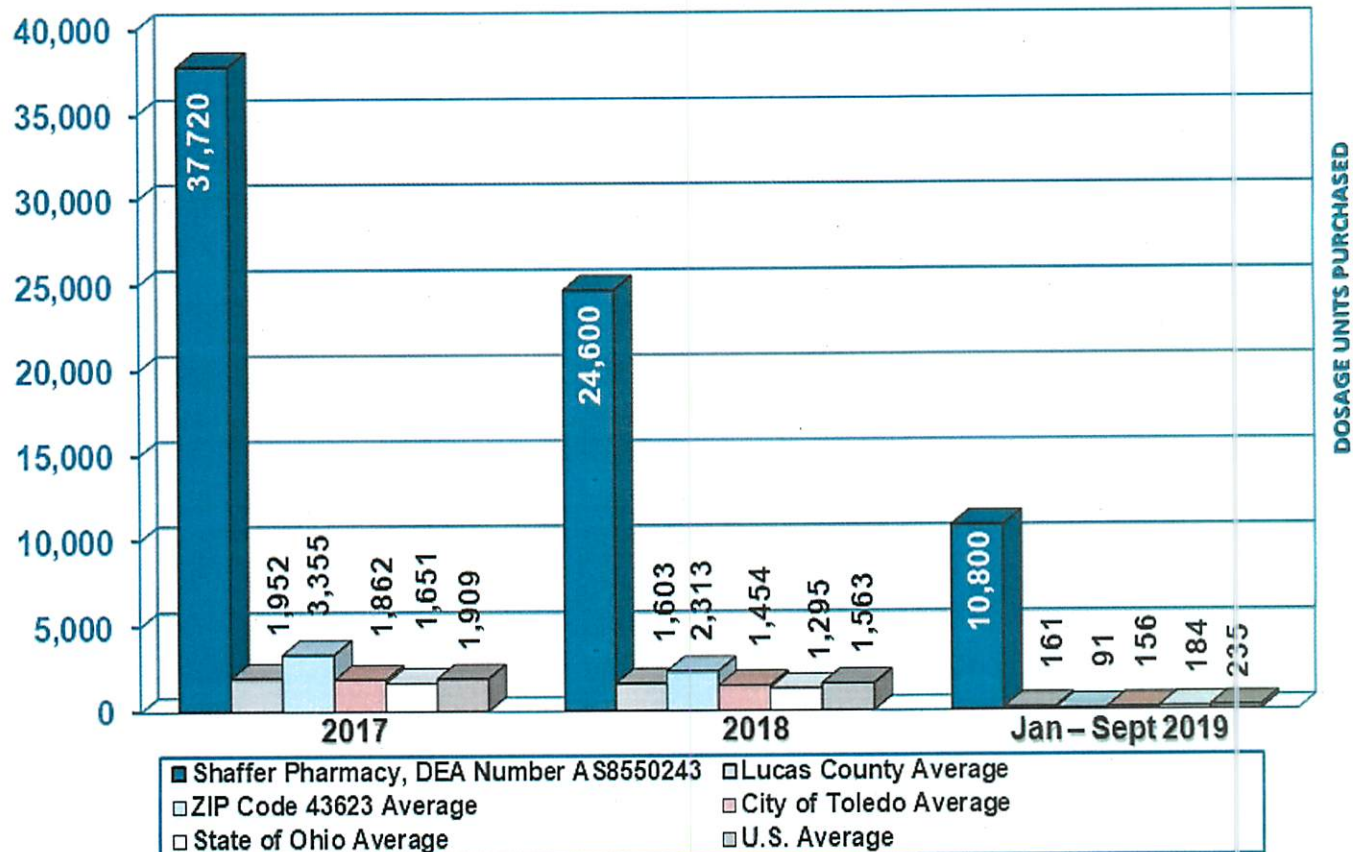


*Targets purchases excluded from averages

Drug Enforcement Administration, Diversion Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

Yearly Comparisons of Oxymorphone Purchases by Pharmacies Jan 2017 to Sept 2019



*Targets purchases excluded from averages

Drug Enforcement Administration, Division Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

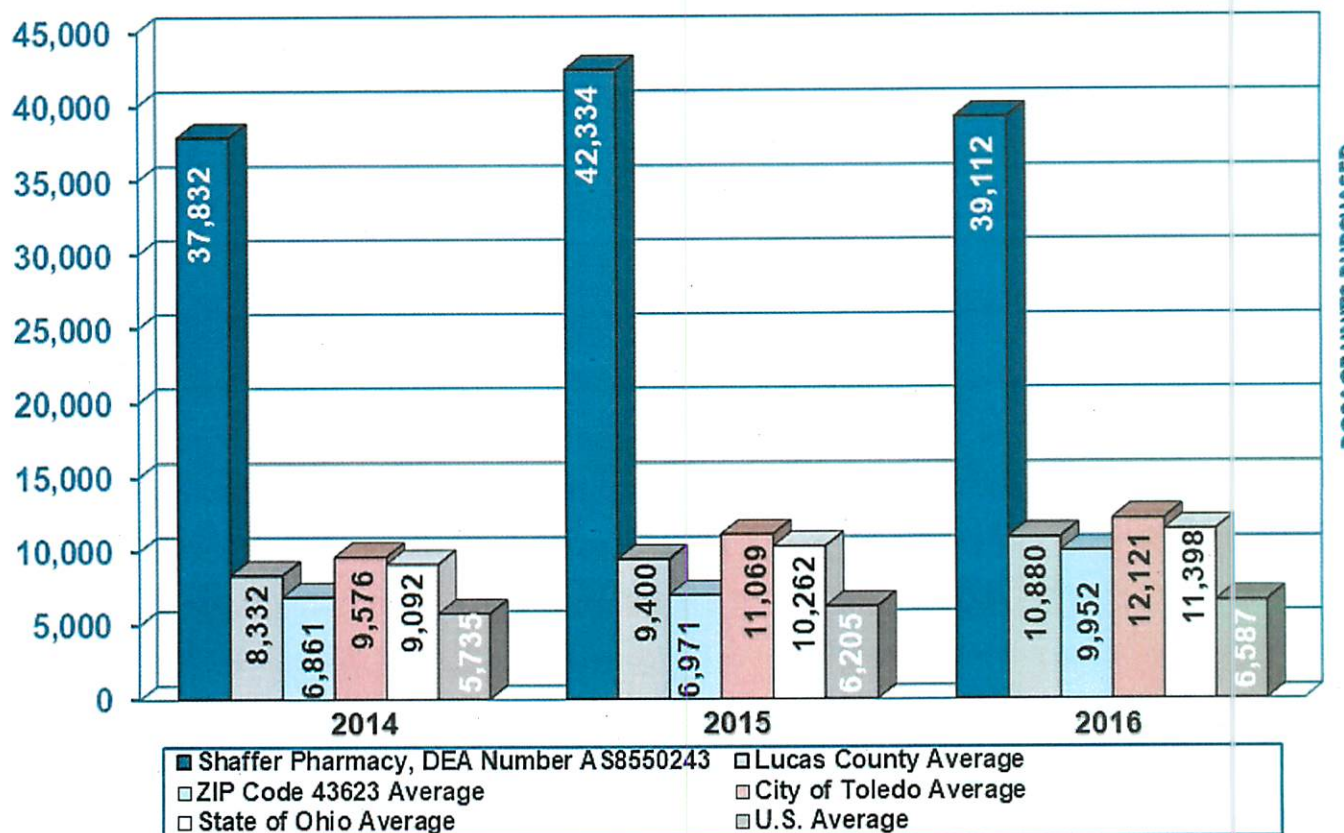
74. The previous charts show that Shaffer Pharmacy is an extreme outlier for purchases of oxymorphone compared to the nationwide, citywide, statewide, Zip code, and countywide averages. In the majority of comparisons, Shaffer Pharmacy purchased ten times or greater the average amount of oxymorphone for a pharmacy.

75. A comparison was made of the oxymorphone purchasing history of Shaffer Pharmacy to other pharmacies in Lucas County, Ohio, where Shaffer Pharmacy is located. Shaffer Pharmacy was the top purchaser of oxymorphone in Lucas County for the entire period

of January 2014 through September 2019. Shaffer Pharmacy purchased at least three times the amount of oxymorphone per year as the next highest purchaser of oxymorphone, up to more than five times the amount of oxymorphone as the next highest pharmacy some years.

76. A comparison was made of Shaffer Pharmacy's purchasing history to purchasing averages for other pharmacies for the period of January 1, 2014 to September 30, 2019. Shaffer Pharmacy's purchases of the schedule III opioid controlled substance buprenorphine, in dosage units, are compared to pharmacy averages in the following charts:

Yearly Comparisons of Buprenorphine Purchases by Pharmacies Jan 2014 to Dec 2016

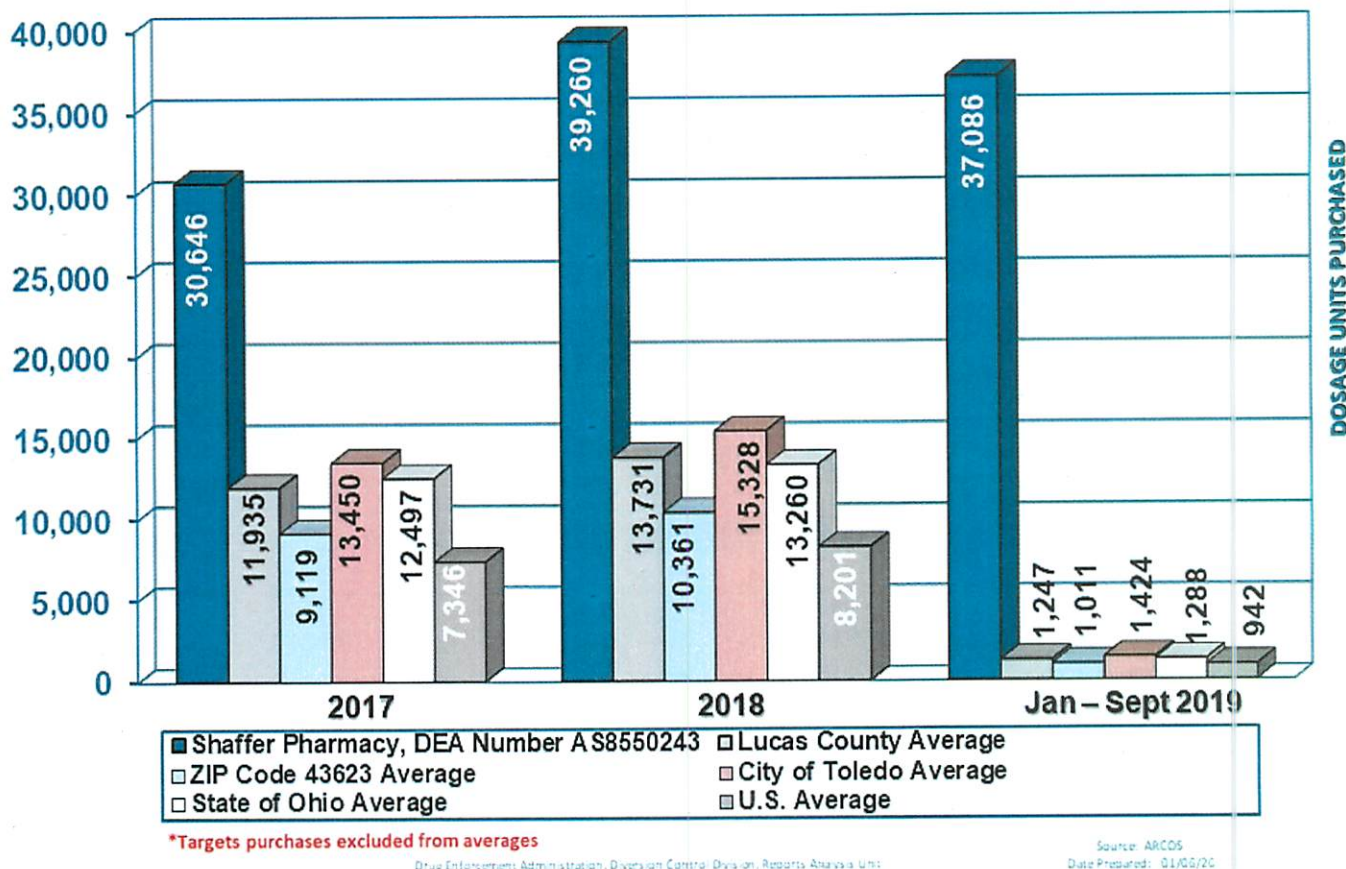


*Targets purchases excluded from averages

Drug Enforcement Administration, Diversion Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

Yearly Comparisons of Buprenorphine Purchases by Pharmacies Jan 2017 to Sept 2019

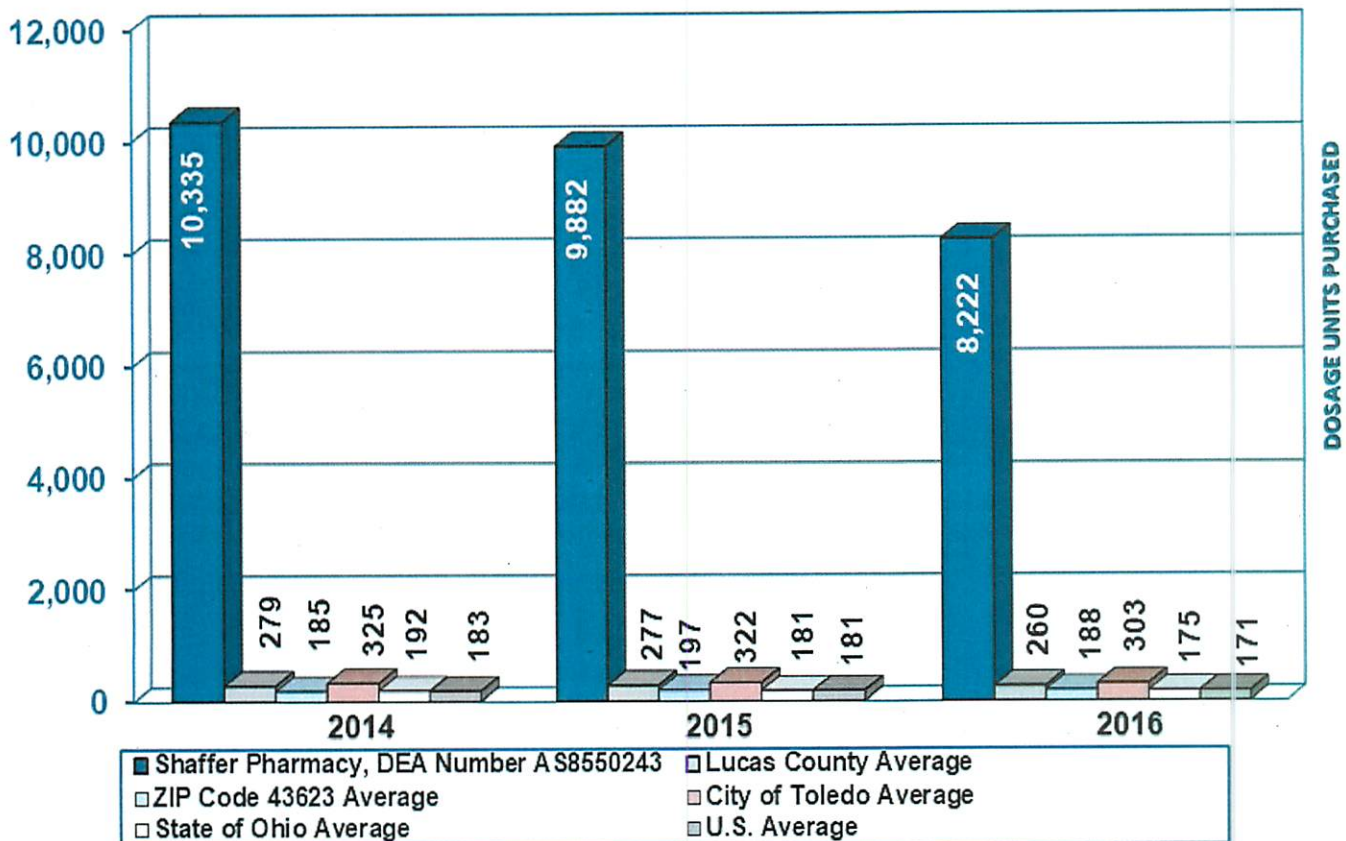


77. The previous charts show that Shaffer Pharmacy is an outlier for purchases of buprenorphine compared to the nationwide, citywide, statewide, Zip code, and countywide averages. In the majority of comparisons, Shaffer Pharmacy purchased three or greater the average amount of buprenorphine for a pharmacy.

78. A comparison was made of Shaffer Pharmacy's purchasing history to purchasing averages for other pharmacies for the period of January 1, 2014 to September 30, 2019. Shaffer

Pharmacy's purchases of the schedule II opioid controlled substance fentanyl (not including Subsys), in dosage units, are compared to pharmacy averages in the following charts:

Yearly Comparisons of Fentanyl (minus Subsys) Purchases by Pharmacies Jan 2014 to Dec 2016

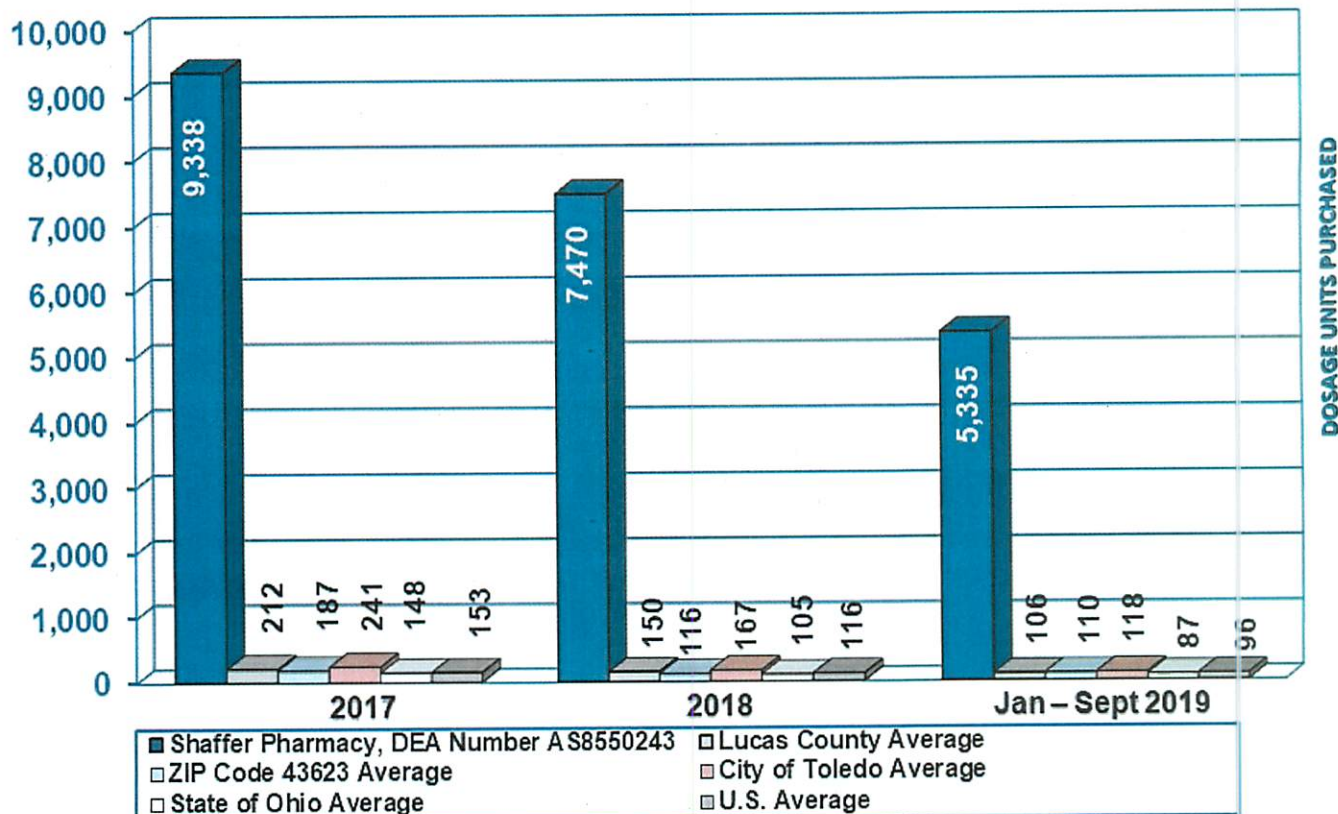


*Targets purchases excluded from averages

Drug Enforcement Administration, Diversion Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

Yearly Comparisons of Fentanyl (minus Subsys) Purchases by Pharmacies Jan 2017 to Sept 2019



*Targets purchases excluded from averages

Drug Enforcement Administration, Diversion Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

79. The previous charts show that Shaffer Pharmacy is an outlier for purchases of fentanyl (excluding Subsys) compared to the nationwide, citywide, statewide, Zip code, and countywide averages. In all comparisons, Shaffer Pharmacy purchased twenty-five times or greater the average amount of fentanyl for a pharmacy.

80. A comparison was made of the fentanyl (excluding Subsys) purchasing history of Shaffer Pharmacy to other pharmacies in Lucas County, Ohio, where Shaffer Pharmacy is located. Shaffer Pharmacy was the second highest purchaser of fentanyl in Lucas County from

January 2014 through September 2019, surpassed only by Heartland Healthcare Services.

Shaffer Pharmacy purchased around twice the amount of fentanyl as the third highest purchaser of fentanyl in Lucas County each year from 2014 through September 2019.

“RED FLAGS: Subsys”

81. Subsys is a brand name for a sublingual spray formulation of the potent opioid fentanyl. It is fifty to one-hundred times more powerful than morphine. Subsys has only one approved indication for use: the management of breakthrough cancer pain in patients with malignancies who are already receiving, and tolerant to, opioid therapy for underlying cancer pain. Subsys should only be prescribed by oncologists and pain specialists knowledgeable in the management of cancer pain.

82. Insys Therapeutics, Inc., (“Insys”) founded in 1990, is the pharmaceutical company that produces and markets Subsys. In 2019, Insys and several former executives were convicted of various crimes, including conspiracy and bribery in the marketing of its Subsys product. The conduct underlying the conviction against Insys and its executives centered on unlawful payments to prescribers as “speaker fees” to drive up the prescribing of Subsys. Insys also made false statements to insurance providers, falsely stating that patients had diagnoses warranting Subsys treatment, when, in fact, Insys knew that individuals did not have such diagnoses.

83. Insys founder, John Kapoor, was among those found guilty for crimes related to this scheme, and was sentenced to five and a half years in prison.

84. Insys agreed to pay \$225 million to the federal government to resolve civil claims and criminal charges arising from the scheme.

85. The Insys scheme was vast and spread across the entire country. A number of practitioners across multiple jurisdictions have pled guilty to, or been found guilty of, accepting bribes and kickbacks from Insys for prescribing Subsys.

86. In September 2020, Dr. Jimmy Henry, MD (DEA #FH2232178) was indicted by a federal grand jury in the Southern District of Ohio on charges of health care fraud conspiracy. The indictment read, in part:

[f]rom in and around September 2015 until at least around January 2019, Jimmy HENRY . . . caused false a fraudulent claims to be submitted for reimbursement to Medicare and the Ohio Medicaid Program for prescription medications that were not medically necessary, not eligible for reimbursement, induced by illegal kickbacks, and issued outside the usual course of professional practice and without a legitimate medical purpose.

87. Shaffer Pharmacy filled 283 prescriptions for Subsys written by Dr. Jimmy Henry between 2015 and 2016.

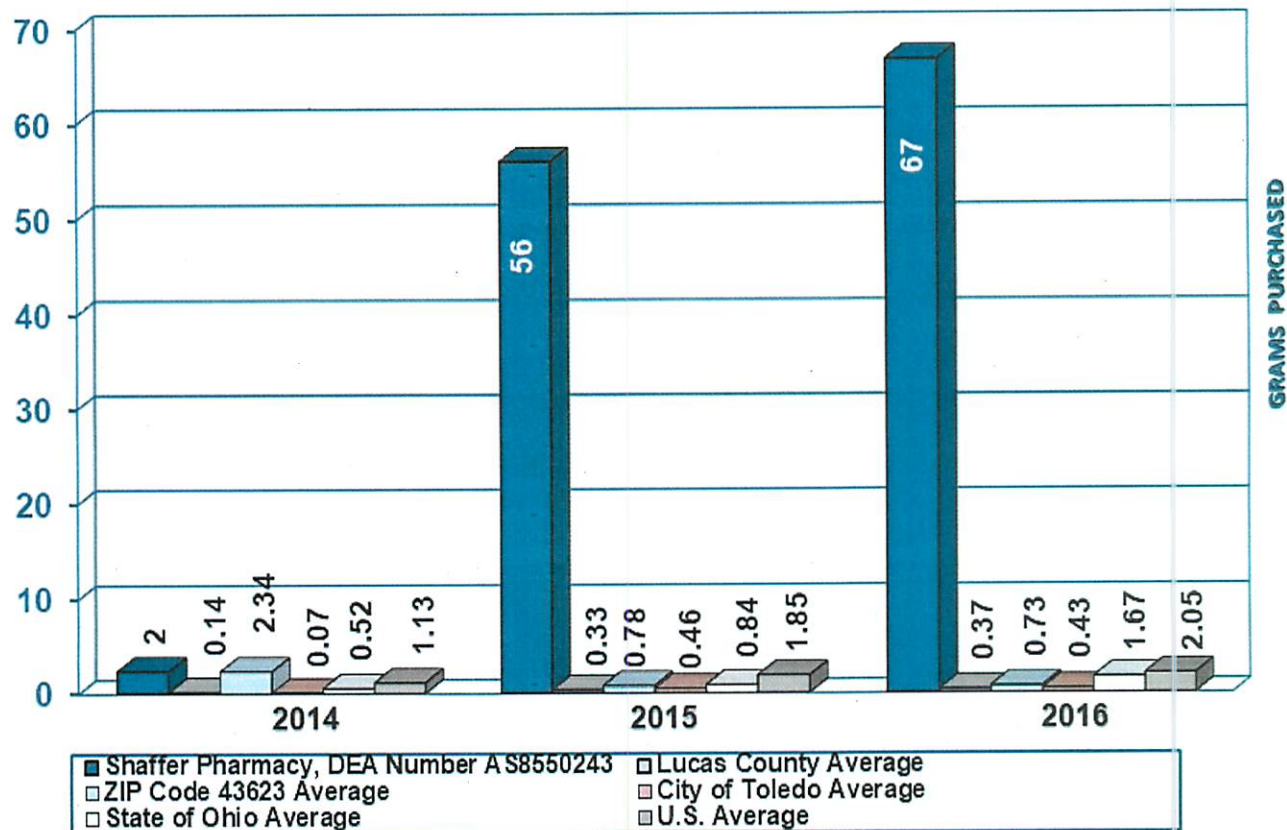
88. More than 8,000 deaths have been reported to the FDA's Adverse Events Reporting System for patients who were taking Subsys. Among these reports are many patient deaths where the "reason for use" includes no cancer diagnosis. "Radiculopathy" and "Osteoarthritis" as well as "Arthralgia," with the statement "Off label use; Death," "Fibromyalgia," even "Back Pain" all appear, with no indication of cancer sequelae.

89. Insys' legal troubles were the subject of national television and print news stories. Therefore, it is a potential red flag when a pharmacy continues to purchase and dispense high volumes of Subsys, in light of the rampant inappropriate/illegal prescribing of the drug.

90. A comparison was made of Shaffer Pharmacy's purchasing history to purchasing averages for all other pharmacies purchasing Subsys, for the period of January 1, 2014 to

September 30, 2019. Shaffer Pharmacy's purchases of the schedule II opioid controlled substance Subsys, in grams, are compared to pharmacy averages in the following charts:

Yearly Comparisons of Subsys Purchases by Pharmacies Jan 2014 to Dec 2016

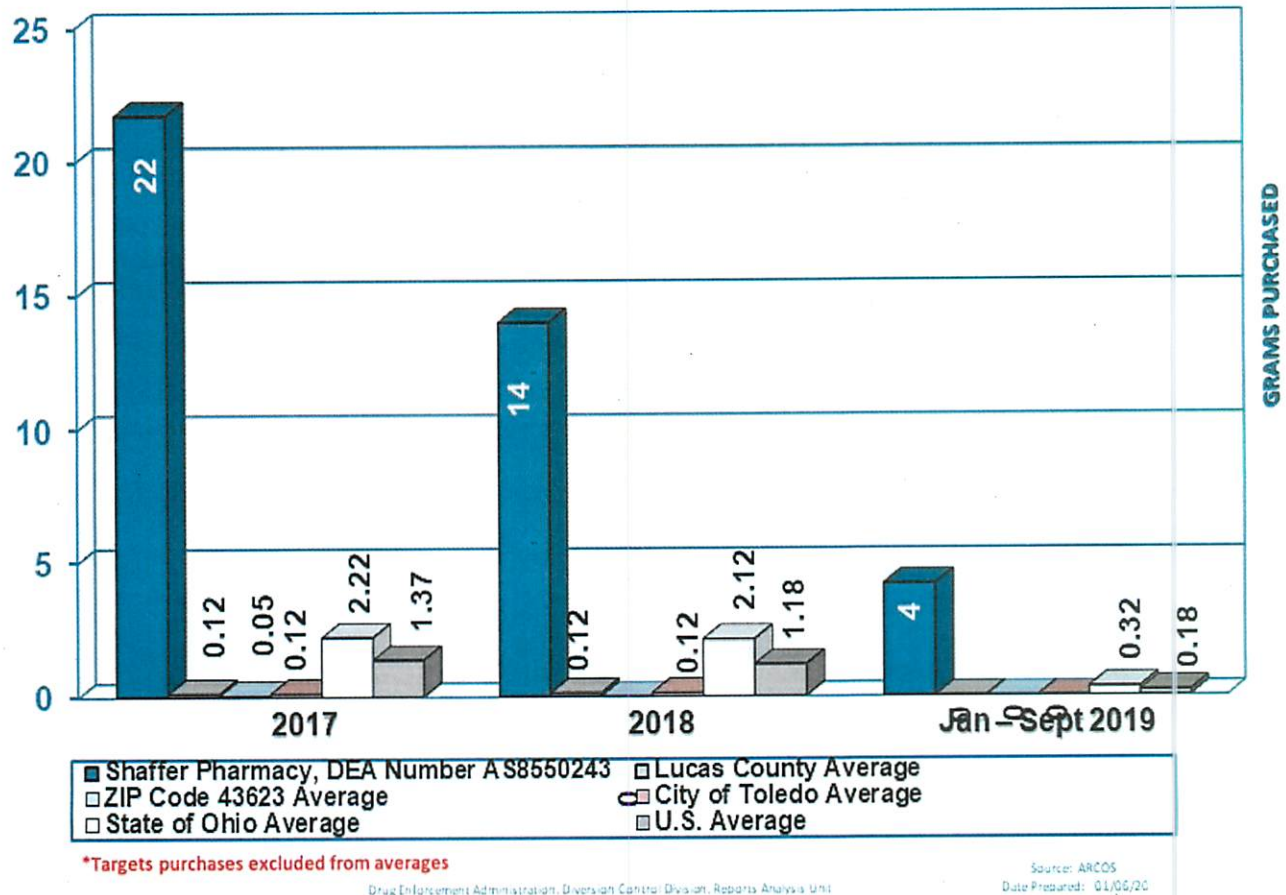


*Targets purchases excluded from averages

Drug Enforcement Administration, Diversion Control Division, Reports Analysis Unit

Source: ARCOS
Date Prepared: 01/06/20

Yearly Comparisons of Subsys Purchases by Pharmacies Jan 2017 to Sept 2019



91. The previous charts show that Shaffer Pharmacy is an outlier for purchases of Subsys compared to the nationwide, citywide, statewide, Zip code, and countywide averages. The average amount of Subsys purchased, in grams, did not exceed 2.05 in the US, and 2.22 in Ohio, meanwhile, Shaffer Pharmacy purchased over 66 grams in one year.

92. In 2014, Shaffer Pharmacy purchased more than three times the amount of Subsys in grams as the second highest purchaser of Subsys in Lucas County, Ohio. In 2015, that divide

widened, with Shaffer Pharmacy purchasing 55.89 grams of Subsys, while the next highest purchasers received 3.12, 2.62 and 1.23 grams of Subsys respectively.

93. In 2018, Shaffer Pharmacy became the only pharmacy purchasing Subsys in its Zip code (43623), and in 2019, Shaffer Pharmacy was the only pharmacy purchasing Subsys in Lucas County, Ohio.

“RED FLAGS: Distributor Notifications”

94. It can be a red flag when controlled substance distributors refuse or cease to do business with a pharmacy due to concerns about their ordering patterns. On January 8, 2020, Amerisource Bergen Drug Company, one of the three pharmaceutical suppliers for Shaffer Pharmacy, sent a letter to the DEA titled “In Re: Termination of Sales of Controlled Substances to Shaffer Pharmacy.” This letter, stated in part,

Following a review of the controlled substance ordering activity of Shaffer Pharmacy, DEA registration AS8550243, several red flags were noted, as follows:

- 43% controlled substances dispensed by total dosage unit.
- 53% of controlled substances dispensed are Oxycodone

As a result, ABDC immediately terminated controlled substance sales to pharmacy on November 21, 2019.

A true and correct copy of the Amerisource Bergen letter to the DEA is attached as Exhibit D to this declaration.

95. It can be a red flag when controlled substance distributors file Suspicious Order reports to the DEA. One of Shaffer Pharmacy’s controlled substance suppliers, Cardinal Health (DEA Registration RO0153609), has filed fifteen suspicious order reports to the DEA for transactions dated between 08/20/2020 and 10/21/2020. These purchases by Shaffer Pharmacy were attempted for one to five bottle of oxycodone and hydrocodone products, in varying strengths, and reported for order frequency or exceeding volume thresholds. A true and correct

copy of the Suspicious Order Transaction System (SORS II) log for Shaffer Pharmacy is attached as Exhibit E to this declaration.

Dated: January 4, 2021

By:



Meredith Carter
Diversion Investigator
United States Drug Enforcement
Administration

<u>Controlled Substance ("CS")</u>	<u>Schedule</u>	<u>Common Brand Names</u>	<u>Title 21 Code of Federal Regulations</u>	<u>The Orange Book, Drug List Section - Page</u>
ACETAMINOPHEN-CODEINE	CS-III	Tylenol With Codeine, Tylenol 3	21 C.F.R. §1308.13(e)(1)(i)	3-4
ALPRAZOLAM	CS-IV	Xanax, Xanax XR	21 C.F.R. §1308.14(c)(2)	3-16
AMPHETAMINE SULFATE (SALTS)	CS-II	Adderall, Adderall XR	21 C.F.R. §1308.12(d)(1)	3-31
BUPRENORPHINE-NALOXONE	CS-III	Suboxone	21 C.F.R. §1308.13(e)(2)(i)	3-65
BUPRENORPHINE	CS-III	Belbuca, Butrans	21 C.F.R. §1308.13(e)(2)(i)	3-64
CARISOPRODOL	CS-IV	Soma	21 C.F.R. §1308.14(c)(7)	3-81
CHLORDIAZEPOXIDE	CS-IV	Librium	21 C.F.R. §1308.14(c)(10)	3-90
CLONAZEPAM	CS-IV	Klonopin	21 C.F.R. §1308.14(c)(12)	3-105
DESMETHYLPHENIDATE	CS-II	FocalinXR	21 C.F.R. §1308.12(d)(4)	3-127
DEXTROAMPHETAMINE SULFATE	CS-II	Dexedrine, Dexedrine ER	21 C.F.R. §1308.12(d)(1)	3-128
DIAZEPAM	CS-IV	Diastat Acudial, Valium	21 C.F.R. §1308.14(c)(17)	3-134
DRONABINOL	CS-III	Marinol	21 C.F.R. §1308.13(g)(1)	3-151
ESZOPICLONE	CS-IV	Lunesta	21 C.F.R. §1308.14(c)(58)	3-170
FENTANYL	CS-II	Duragesic (Patch), Subsys (Spray), Actiq (injection)	21 C.F.R. §1308.12(c)(9)	3-185-86
HYDROCODONE BITARTRATE	CS-II	Zohydro ER	21 C.F.R. §1308.12(b)(1)(vi)	3-225

DECL.
EXHIBIT

A

HYDROCODONE BITARTRATE-HOMATROPINE	CS-II	Tussigon (syrup), Hycodan (syrup)	21 C.F.R. §1308.12(b)(1)(vi)	3-219
HYDROCODONE BITARTRATE-IBUPROFEN	CS-II	Reprexain	21 C.F.R. §1308.12(b)(1)(vi)	3-226, 6-214
HYDROMORPHONE	CS-II	Exalgo, Dilaudid	21 C.F.R. §1308.12(b)(1)(vii)	3-229, 6-221
LISDEXAMFETAMINE DIMESYLATE	CS-II	Vyvanse	21 C.F.R. §1308.12(d)(5)	3-268-69
LORAZEPAM	CS-IV	Ativan	21 C.F.R. §1308.14(c)(32)	3-271
METHADONE HYDROCHLORIDE	CS-II	Methadose, Dolophine	21 C.F.R. §1308.12(c)(15)	3-286-87
METHYLPHENIDATE	CS-II	Daytrana	21 C.F.R. §1308.12(d)(4)	3-290
MODAFINIL	CS-IV	Provigil	21 C.F.R. §1308.14(f)(7)	3-304
MORPHINE SULFATE	CS-II	Morphine	21 C.F.R. §1308.12(b)(1)(ix)	3-306-08
OXYCODONE	CS-II	Xtampza	21 C.F.R. §1308.12(b)(1)(xiv)	3-336
OXYCODONE HYDROCHLORIDE	CS-II	Roxicodone, Oxycontin	21 C.F.R. §1308.12(b)(1)(xiv)	3-336-37
OXYMORPHONE HYDROCHLORIDE	CS-II	Opana	21 C.F.R. §1308.12(b)(1)(xv)	6-317
PHENTERMINE HYDROCHLORIDE	CS-IV	Adipex-P	21 C.F.R. §1308.14(f)(9)	3-348-49
TAPENTADOL HYDROCHLORIDE	CS-II	Nucynta	21 C.F.R. §1308.12(c)(28)	3-412, 6-385
TRAMADOL HYDROCHLORIDE	CS-IV	Conzip	21 C.F.R. §1308.14(b)(3)	3-430
TRIAZOLAM	CS-IV	Halcion	21 C.F.R. §1308.14(c)(55)	3-435

ZOLPIDEM TARTRATE	CS-IV	Edluar, Zolpimist, Ambien	21 C.F.R. §1308.14(c)(57)	3-452
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License Look Up

12/29/2020 3:48 PM

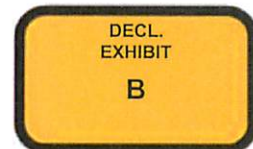
SHAFFER PHARMACY, INC.

Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 3
License Number	020157850
License Issue Date	01/26/1979
License Expiration Date	03/31/2021
License Effective Date	04/01/2019
Street Address	3900 SUNFOREST CT SUITE 124
City	TOLEDO
State	OH
Zipcode	43623
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
		Active		

Current date & time: 12/29/2020 3:48 PM



Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

Master Detail

Page 1 of 1

[Record Status](#) | [Master Information](#) | [History Information](#) | [Images](#) | [Investigative Information](#) |
Master Information for DEA Number: AS8550243

STATUS: ACTIVE PENDING

CURRENTLY UNDER INVESTIGATION

Expiration Date: **02/28/2021**
 Last Renewed: 01/06/2018
 Cert. Last Issued: 01/06/2018
 Registration Date:
 Date of Record: 01/01/1990

Office Name: **CLEVELAND (05)**
 Web Tracking Id: 7105123
 E-Signature: THOMAS J. TADSEN
 Cert. Print: NO
 Carfentanil: NO
 NADDIS No:

ARCOS Status: NONREPORTABLE
 CMEA Status: NO
 DTL Status: NO
 QUOTA Eligible: NO
 Marijuana Grower: NO

SECTION 1 & 2 UPDATE

Business Activity: RETAIL PHARMACY
 Business or Facility Name: SHAFFER PHARMACY
 Additional Company Info.:
 Registrant Address: 3900 SUNFOREST CT
 TOLEDO, OH 43623
 Phone No.: (419) 473-0891 EXT.:
 Contact Name: THOMAS TADSEN
 Contact Cell: (419) 297-4416
 SSN: 294463219
 NPI:

Additional Company Info.:

MailTo Address: 3900 SUNFOREST CT
 TOLEDO, OH 43623
 Fax No.: (419) 473-0899
 Contact Email: SHAFFERPHARMACY@GMAIL.COM
 Tax ID: 34-0878119

SECTION 3 & 4 UPDATE

	1	2	2N	3	3N	4	5	L1
Drug Schedules:	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Restricted/Limited:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Order Forms Requested: ☐

License Issuing State: OH

State License No.: 020157850
 CS License No.:

Exp. Date: 03/31/2018
 Exp. Date:

SECTION 5 UPDATE**There are no liabilities for this registrant.****SECTION 6 & 7**

Payment Type: CREDIT CARD

Payment Amount: 731

Payment Status: PAID

DECL.
 EXHIBIT
 C

https://csa.diversion.sbu.dea.doj.gov:8081/csa/csa_master_detail?p_master_id=1096277

12/29/2020



AmerisourceBergen Corporation
Corporate Security & Regulatory Affairs
1300 Morris Drive
Chesterbrook, PA 19087-5594
www.amerisourcebergen.com

David May
Vice President, CSRA
Phone 910-986-5061
Fax 877-479-6650
dmay@AmerisourceBergen.com

January 8, 2020

Keith Martin
Special Agent in Charge
Detroit Division
Drug Enforcement Administration
431 Howard Street
Detroit, MI 48226

In Re: Termination of Sales of Controlled Substances to Shaffer Pharmacy.

Dear SAC Martin,

AmerisourceBergen Drug Corporation (ABDC) is committed to meeting all legal and regulatory requirements imposed upon it as a wholesale distributor and constantly strives to protect the integrity of our country's pharmaceutical supply chain. As such, ABDC follows a procedure of due diligence and continuous oversight of controlled substances sales to its registrant customers. Through the use of advanced analytics and other means, ABDC will sometimes discover purchasing activities of interest that are not able to be resolved and or adequately explained by the customer. Under such circumstances, ABDC will terminate the customer's ability to order controlled substances from ABDC and add the customer to ABDC's Do Not Ship List.

Following a review of the controlled substance ordering activity of Shaffer Pharmacy, DEA registration AS8550243, several red flags were noted, as follows:

- 43% controlled substances dispensed by total dosage unit.
- 53% of controlled substances dispensed are Oxycodone.

As a result, ABDC immediately terminated controlled substance sales to pharmacy on November 21st, 2019.

Please let me know if you or any members of your staff have any questions regarding this action by contacting me directly at (910) 986-5061 or dmay@AmerisourceBergen.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'David May'.

David May
Vice President
Corporate Security & Regulatory Affairs
AmerisourceBergen Corporation

DECL.
EXHIBIT

D

DEPARTMENT OF JUSTICE
 DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL
 SUSPICIOUS ORDER TRANSACTION QUERY RESULTS
 RUN DATE: 23-OCT-20

Reportee Name	Reportee DEA No.	Reportee Address	Reportee Actual Trk	Reportee City	Reportee State	Reportee Zip	Reportee Office Code	Reportee Office	Reportee Division
CARDINAL HEALTH	RO0153609	71 MIL-ACRES DR		WHEELING	WV	26003	CHARLESTON 44		LOUISVILLE
CARDINAL HEALTH	RO0153609	71 MIL-ACRES DR		WHEELING	WV	26003	CHARLESTON 44		LOUISVILLE
CARDINAL HEALTH	RO0153609	71 MIL-ACRES DR		WHEELING	WV	26003	CHARLESTON 44		LOUISVILLE
CARDINAL HEALTH	RO0153609	71 MIL-ACRES DR		WHEELING	WV	26003	CHARLESTON 44		LOUISVILLE
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CARDINAL HEALTH	RO0153609	71 MIL-ACRES DR		WHEELING	WV	26003	CHARLESTON 44		LOUISVILLE
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CARDINAL HEALTH	RO0153609	71 MIL-ACRES DR		WHEELING	WV	26003	CHARLESTON 44		LOUISVILLE
CARDINAL HEALTH	RO0153609	71 MIL-ACRES DR		WHEELING	WV	26003	CHARLESTON 44		LOUISVILLE

[illegible]

Transaction Date	NDC No	Trade Name	Ingredient	CSA Drug Sched	Formula/Strength
08/20/2020	53746-0110-05	HYDROCODONE BIT./ACETAMINOPHEN TABS. 10MG/325MG	HYDROCODONE BITARTRATE HEMIPENTAHYDRATE	2	10 MILLIGRAM
09/09/2020	53746-0109-05	HYDROCODONE BIT./ACETAMINOPHEN TABS. 5MG/325MG	HYDROCODONE BITARTRATE HEMIPENTAHYDRATE	2	5 MILLIGRAM
09/15/2020	00406-0522-05	OXYCODONE HCL/ACETAMINOPHEN 7.5MG/325MG TABLET; 500 TAB BOTTLE	OXYCODONE HYDROCHLORIDE	2	7.5 MILLIGRAM
09/15/2020	00406-0523-01	OXYCODONE HCL/ACETAMINOPHEN 10MG/325MG TABLET; 100 TAB BOTTLE	OXYCODONE HYDROCHLORIDE	2	10 MILLIGRAM
09/15/2020	10702-0008-01	OXYCODONE HCL 15MG USP TABLETS	OXYCODONE HYDROCHLORIDE	2	15 MILLIGRAM
09/15/2020	10702-0056-01	OXYCODONE HCL 10MG TABLETS USP	OXYCODONE HYDROCHLORIDE	2	10 MILLIGRAM
09/15/2020	10702-0057-01	OXYCODONE HCL 20 MG TABLETS USP	OXYCODONE HYDROCHLORIDE	2	20 MILLIGRAM
09/15/2020	59011-0440-10	OXYCONTIN 40MG OXYCODONE HCL CR TABLET	OXYCODONE HYDROCHLORIDE	2	40 MILLIGRAM
10/20/2020	10702-0009-01	OXYCODONE HCL 30MG USP TABLETS	OXYCODONE HYDROCHLORIDE	2	30 MILLIGRAM
10/20/2020	53746-0109-05	HYDROCODONE BIT./ACETAMINOPHEN TABS. 5MG/325MG	HYDROCODONE BITARTRATE HEMIPENTAHYDRATE	2	5 MILLIGRAM
10/21/2020	10702-0009-01	OXYCODONE HCL 30MG USP TABLETS	OXYCODONE HYDROCHLORIDE	2	30 MILLIGRAM
10/21/2020	43386-0432-01	OXYCODONE HYDROCHLORIDE 5MG TABLET; 100 TAB BOTTLE	OXYCODONE HYDROCHLORIDE	2	5 MILLIGRAM
10/21/2020	47781-0196-05	OXYCODONE HCL/ACETA 5MG/325MG TABLET; 500 TABLETS	OXYCODONE HYDROCHLORIDE	2	5 MILLIGRAM
10/21/2020	47781-0229-05	OXYCODONE HCL/ACETAMINOPHEN 7.5MG/325MG TABLET; 500 TAB BOTTLE	OXYCODONE HYDROCHLORIDE	2	7.5 MILLIGRAM
10/21/2020	47781-0230-05	OXYCODONE HCL/ACETAMINOPHEN 10MG/325MG TABLET; 500 TAB BOTTLE	OXYCODONE HYDROCHLORIDE	2	10 MILLIGRAM

Pack Size	Total	Dose Code	Quantity	Formula	Strength	Reporting Reason	Reason Explanation	Transaction Dates	Transaction Code
MILLIGRAM	9193	1	MILLIGRAM	10	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$
MILLIGRAM	9193	1	MILLIGRAM	5	OTHER	PRIMARY WHLSR FOR ITEM/FAMILY AND VOL EXCEEDS METHODOLOGY, BASED ON INFO		None	\$
MILLIGRAM	9143	1	MILLIGRAM	7.5	OTHER	PRIMARY WHLSR FOR ITEM/FAMILY AND VOL EXCEEDS METHODOLOGY, BASED ON INFO		None	\$
MILLIGRAM	9143	1	MILLIGRAM	10	OTHER	PRIMARY WHLSR FOR ITEM/FAMILY AND VOL EXCEEDS METHODOLOGY, BASED ON INFO		None	\$
MILLIGRAM	9143	2	MILLIGRAM	15	OTHER	PRIMARY WHLSR FOR ITEM/FAMILY AND VOL EXCEEDS METHODOLOGY, BASED ON INFO		None	\$
MILLIGRAM	9143	5	MILLIGRAM	10	OTHER	PRIMARY WHLSR FOR ITEM/FAMILY AND VOL EXCEEDS METHODOLOGY, BASED ON INFO		None	\$
MILLIGRAM	9143	3	MILLIGRAM	20	OTHER	PRIMARY WHLSR FOR ITEM/FAMILY AND VOL EXCEEDS METHODOLOGY, BASED ON INFO		None	\$
MILLIGRAM	9143	1	MILLIGRAM	40	OTHER	PRIMARY WHLSR FOR ITEM/FAMILY AND VOL EXCEEDS METHODOLOGY, BASED ON INFO		None	\$
MILLIGRAM	9143	2	MILLIGRAM	30	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$
MILLIGRAM	9193	1	MILLIGRAM	5	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$
MILLIGRAM	9143	2	MILLIGRAM	30	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$
MILLIGRAM	9143	1	MILLIGRAM	5	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$
MILLIGRAM	9143	1	MILLIGRAM	5	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$
MILLIGRAM	9143	1	MILLIGRAM	7.5	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$
MILLIGRAM	9143	1	MILLIGRAM	10	FREQUENCY	ITEM ORDERED AT END OF ACCRUAL PERIOD		None	\$